Remarks

This is in response to the Office Action mailed January 31, 2007 in the subject application.

Applicant acknowledges the removal of the Schrier reference (U.S. Pat. No. 5,833,599) based on the previously filed declarations under 37 CFR § 1.131.

Claims 97-123 were pending at the time of the mailing of the instant Office Action. Applicant hereby requests allowance based on the claim amendments and representations submitted herein.

Claim Rejections - 35 USC § 102

Claims 97-106 and 114-120 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Renvall (WO 91/024447). The subject application contains (3) three independent claims, claims 97, 101, and 119.

Claims 97 and 101 have been amended. Support for the amendments is indicated by referencing, in brackets, paragraph numbers in the published application (U.S. Patent Application 2002/0042726).

Claim 97, as now presented, recites:

A computer-implemented method for assembling a prescription, the method comprising:

providing an electronic database of drugs; [para. 0092]

electronically storing a patient identifier in a computer memory medium;

using the patient identifier, electronically identifying from the database of drugs, a list of drugs approved by a drugs benefit provider; [para. 0278]

electronically associating with the patient identifier, a drug selected from the list of drugs approved by a drugs benefit provider;

electronically associating a dosage for the selected drug, with the patient identifier and the selected drug; and

retrieving and outputting the associated selected drug and dosage associated with a patient identifier.

The current Office Action purports that Renvall discloses the electronic association of the drug selected from the list of drugs approved by a drugs benefit provider. The Office Action cites Figure 2, and page 5, lines 22-27 of the Renvall reference. However, as will be explained, the citation does not provide for any electronic "identifying" or "associating" as provided for in the claimed invention.

The Office Action also incorrectly states that the manner of forming the drug list is not pertinent. This is an incorrect

characterization. The method of the present invention, as claimed, requires "using the patient identifier, electronically identifying from the database of drugs, a list of drugs approved by a drugs benefit provider."

The specification of the present invention states:

> By means of the system, drug formulary guidelines effectively adapt to the user's prescribing patterns or can be followed effortlessly by the prescriber. This desirable prescriber-centricity can be obtained by giving priority to the prescriber's personal or custom lists or, better still if they are a subset of these, to the patient's history lists, and system-identifying patient-formulary preferences on those lists for easy final picking by the prescriber. Where the prescriber is selecting a drug providing effective therapy for a just-specified condition, the above procedure may often clearly identify a single drug meeting all requirements or may result in a short list of a very small number of drugs for final selection. Where no drug is listed as meeting all requirements, the system may so alert the user and suggest formulary drugs not on the doctor-specific lists or ask the user whether they wish to review appropriate non-formulary drugs from their personal or custom lists.

(Published Application, at paragraph 0278)

> Typically, drug formularies comprise lists of preferred drugs whose costs will be borne by a drugs benefit house.

(Published Application, at paragraph 0007]

Formulary, refers to a list of drugs. The list may be a list of physician preferred drugs, or a list of preferred dugs provided by a drugs benefit provider.

In the claimed invention, the patient identifier electronically associates a patient with a specific formulary preferred drug for that patient's drug benefit provider. According to the present invention, when a prescriber inputs the patient identifier, a specific list of approved drugs based on the patient's drugs benefit provides is then accessed. Thus, the "using the patient identifier, electronically identifying from the database of drugs, a list of drugs approved by a drugs benefit provider" and "electronically associating with the patient identifier, a drug selected from the list of drugs approved by a drugs benefit provider" are steps in the method of the claimed invention. There is no need, as purported in the Office Action, to have a step requiring "approving drugs." The drugs have already been approved and are in the list of preferred (e.g., approved) drugs provided by the drug benefit provider. Although, various therapies may exist for a given condition, the drug benefits provider typically has preferred pricing for specific therapies. As stated in para. [0278] of the specification of the subject application (as published) "the system may so alert the user and suggest formulary drugs." In using the method of the present invention, the prescriber is alerted to formulary preferred drugs for the patient's drugs benefit provider.

These electronic "identifying" and "associating" steps are not taught in the Renvall reference.

Renvall teaches an electronic barcode reader wherein the user scans a barcode associated with a particular patient and then selects a barcode (corresponding to a therapy) to be scanned for a specific therapy to be used for that patient. Renvall discloses a user manually selecting a bar code to be scanned from a plurality of bar codes available in a bar code catalog (Renvall page 6, lines 26-30 and page 7, line 33). The user selects a catalog page and scans a bar code into a reader.

In summary, Renvall allows a prescriber to manually select therapy from a list in a bar code catalog. There is nothing in the teaching of Renvall that directs the prescriber to a preferred therapy for a patient based on the patients drugs benefit provider formulary preference.

Nothing in the disclosure of Renvall describes the compilation and/or display of preferred therapy based on the patient identifier and electronic association of the patient identifier with an approved drug list provided by a drug benefit provider. There is no teaching or suggestion anywhere in Renvall for the electronic association of a drug selected from a list of drugs approved by a drugs benefit provider with the patient identifier as provided for in the subject application. A rejection under 35 USC § 102(b) requires each and every element of the claim to be taught. Renvall is deficient in that it does not teach at least the "using the patient identifier, electronically

identifying from the database of drugs, a list of drugs approved by a drugs benefit provider" or the "electronically associating with the patient identifier, a drug selected from the list of drugs approved by a drugs benefit provider" elements from pending claim 97.

Claim 101 requires:

A method for assembling an electronic prescription, comprising the steps of:

providing an electronic database of drugs; [para. 0092]

electronically obtaining a patient identifier converted to electronic data;

electronically retrieving from the database of drugs, a list of drugs approved by a drugs benefit provider for the patient associated with the patient identifier, and the identity of at least one prescribed drug associated with the patient identifier, the at least one prescribed drug being selected from the list of drugs approved by a drugs benefit provider; [para. 0278]

electronically retrieving a dosage for the at least one prescribed drug associated with the at least one prescribed drug and the patient identifier;

storing the at least one prescribed drug, the dosage and the patient identifier in an electronic memory; and

outputting at least the at least one prescribed drug.

Applicant's prior argument asserting the manual bar code reader of Renvall has no disclosure providing "electronically retrieving from the database of drugs, a list of drugs approved by a drugs benefit provider for the patient associated with the patient identifier, and the identity of at least one prescribed drug associated with the patient identifier" also applies to the invention as claimed in claim 101 of the subject application. Renvall only provides for electronic compilation of data based on manual selection and scanning of bar codes from a collection of bar codes. The user of the Renvall device has no way of knowing "the identity of at least one prescribed drug associated with the patient identifier…selected from the list of drugs approved by a drugs benefit provider" as now claimed. Renvall is deficient in the failure to teach or disclose these elements of the claim.

Claim 119 requires:

> electronically storing at least a first patient record including at least one prescribed drug selected from a list of drugs approved by a drugs benefit provider and a prescriber identifier representing the user that selected the at least one prescribed drug;
>
> electronically storing at least a second patient record including at least one prescribed drug selected from a list of drugs approved by a drugs benefit provider and a prescriber identifier representing the user that selected the at least one prescribed drug;
>
> aggregating data from the at least a first patient record with data from the at least a second data patient record to form an aggregated data record; and
>
> outputting the aggregated data record.

As stated above with respect to claims 97 and 101, Renvall does not teach or disclose the prescribed drug selected from a list of drugs approved by a drugs benefit provider. Claim 119 requires "aggregating data from the at least a first patient record with data from the at least a second data patient record to form an aggregated data record." Renvall does not teach or dislcose this aggregation. Renvall only teaches creation of multiple records when a doctor makes rounds and inputs information for each patient (page 7, line 28). Renvall does not teach the records of multiple patients may be combined "to form an aggregated data record" as claimed in claim 119.

Further, Renvall discloses that a doctor using a bar code reader for many patients during rounds is creating a separate data record for each patient. There is no disclosure anywhere in Renvall to compile the data of different patients "to form an aggregated data record" as claimed in claim 119 of the subject application.

Because Renvall fails to teach each and every element of claims 97, 101 and 119, the independent claims of the subject application, a rejection under 35 U.S.C. § 102(b) cannot be properly applied. Applicant respectfully asserts that because independent claims 97, 101, and 119 are not anticipated by Renvall, dependant claims 98-100, 102-106, 114-118, and 120, as rejected by the current Office Action, cannot be the basis for a rejection under 35 USC 102(b). Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claim Rejections - 35 USC § 103

Claim 107 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall in view of Howsen (U.S. Patent No. 5,088,891). Claim 107 is a dependent claim that depends on Claim 101.

As stated above, Renvall does not teach or suggest the method set forth in pending claim 101. Housen is cited to disclose a system/method wherein the patient information is associated with drug interaction information/allergies (column 16, lines 36-40). But, Housen does not teach claim 107 (as purported in the Action). Housen provides for a computer query to a drug database for dosage range errors and adverse drug interactions (column 16, lines 36-40). Further, claim 107, in addition to requiring all the elements of claim 101 from which it depends, requires electronic association of allergy or interaction information regarding the patient or drug formulary. While Howsen may provide information on adverse drug interactions, Howsen does not have any teaching or suggestion for the allergy or interaction information based on drug selected from a drug formulary electronically associated with a patient.

The subject application teaches, in para. [0220]

> A further valuable feature of the novel prescription management system described herein is an ability to review a completed prescription for contraindications, or relative contraindications, such as patient allergies to the prescribed drug and such as possible drug-to-

drug interactions with other drugs the patient has previously been prescribed.

Howsen teaches a generalized data base having adverse drug interactions. Claim 107 provides the system alerts based on the particular patient and drugs prescribed. Thus, a patient under the care of more than one medical professional is protected when medical professional is alerted by "electronically associating with the patient identifier allergy or drug interaction information regarding the patient" as claimed in claim 107. Howsen does not provide for any electronic association of information with a patient. Thus, a prescriber may query the system of Housen and receive interaction information, but without the method of claim 107, the prescriber has no electronic association and warning if there is a concern for the particular patient being treated.

There is no teaching, suggestion, or motivation to modify the references of Renvall in view of Housen to arrive at "electronically associating with the patient identifier allergy or drug interaction information regarding the patient," as claimed in the subjection application. Without a proper teaching, suggestion, or motivation to modify, a rejection under 35 U.S.C. § 103(a) cannot be properly applied. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 108-112 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall in view of "Data hard to get, has many applications" (hereinafter "DATA").

Claims 108-112 are dependant claims with dependency referring back to independent Claim 101. Renvall does not teach the method of claim 101 as discussed above.

DATA is cited allegedly for assembling prescription information. Applicant respectfully points out that DATA does not have any disclosure related to electronic retrievals of formulary information and formulary preferred drugs, as claimed in the subject application. The Office Action incorrectly cites paragraphs 22-25 as teaching assembling from a plurality of sources, drug formulary data, and preferred drugs for a condition. DATA teaches assembly of information from plan sponsors. DATA does not teach or suggest access to remote databases as claimed in claim 108; DATA does not teach or suggest the patient history record retrieved from multiple remote databases as claimed in claim 109; DATA does not teach or suggest the issuing of a drug benefit plan or drug formulary as claimed in claim 110; DATA does not teach accessing databases of drug formulary information as claimed in claim 111; and DATA does not teach prescribing a drug according to formulary guidelines as claimed in claim 112.

Absent any teaching, suggestion, or motivation to modify a rejection under 35 U.S.C. § 103(a) cannot be properly applied.

Applicant respectfully requests reconsideration and withdrawal of this rejection.

As the Office Action further cites rejections of Claims 111 and 112 over Renvall in view of DATA, and Claims 111-112 depend ultimately on Claim 101, in view of the fact that Applicant has established Claim 101 is patentable over the Renvall reference in view of DATA, dependant Claims 111 and 112 are subsequently patentable as well.

Claims 113 and 123 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall in view of Official Notice. Claim 113 depends ultimately on independent Claim 101. Claim 123 depends on independent Claim 119. Each of these claims required electronic access to at least one prescribed drug selected from a list of drugs approved by a drugs benefit provider.

Claim 113 is dependant on independent Claim 101. Applicant asserts that as independent claim 101 is patentable over Renvall, Claim 113 dependant thereon, is also patentable.

Claim 123 depends on independent Claim 119.

There is no disclosure anywhere in Renvall for an electronic storing of a patient record including a drug selected based on preferred formulary information for the drug benefit provider of a particular patient, nor is there disclosure for creating the

aggregated data record of the claimed invention. As stated above, Renvall is a barcode reader whereby the user manually selects a barcode to input information into the reader. The Office Action alleges it is "well known" to sell lead information and that this well known aspect renders the aggregation of data to be obvious. Applicant respectfully traverses the characterization. Because the aggregation of data from multiple patient records to form an aggregated data record is not taught or suggested by Renvall, the selling of the aggregated data record also is not obvious.

Applicant asserts that rejecting Claim 113 and 123 in view of Official Notice is improper. The MPEP § 2144.03 provides

> Official Notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well known, or to be common knowledge, in the art are cable of instant unquestionable demonstration as being well known

The Office Action purports that

> websites often track shopping patterns of users and provide this information to other entities to better target shoppers" (Page 12, paragraph 10).

Applicant objects to this characterization because it is not common knowledge, nor is it capable of instant and unquestionable demonstration as being well know, that websites in 1993 (the date of invention) were capable of performing the tracking cited in the Office Action. Computers, websites, and the Internet, have changed dramatically since the 1993, date of the present invention. Because the tracking cited in the Office Action is not capable of instant and unquestionable

demonstration as being well known, Applicant asserts that an obviousness rejection over Renvall in view of Official Notice cannot properly be applied.

Claims 121 and 122 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall. Applicant respectfully asserts that because Claims 121 and 122 depend on Claim 119, and as stated above Claim 119 is patentable over the Renvall reference, Claims 121 and 122 are also patentable over Renvall.

The Office Action admits

> Renvall does not expressly disclose sorting the aggregated report by particular parameters" (Page 12, paragraph 11).

The Office Action summarily dismisses the scope of the subject claims as saying that aggregated reports sorted by various parameters, including patient medication, patient data, date, and prescriber would be obvious. There is no teaching or suggestion in Renvall (a simple barcode reader and data assembler) to practice the method claimed in Claims 119, 121, and 122, because Renvall is merely a reader that outputs stored information from scanned bar codes and multiple patient records, but does not teach or suggest the records aggregation to form a data record, as provided in the claims. Because the bar code reader of Renvall is deficient, in that it does not teach or suggest the method of the claimed invention, nor is there a motivation to modify, the Official Notice does not cure the deficiency, and the relied upon Official Notice is improper, a rejection under 35 U.S.C. § 103(a) cannot properly be applied.

Applicant respectfully request reconsideration and withdrawal of this rejection.

Based on the Amendments presented herein, Applicant respectfully asserts the application is now in condition for allowance. If the Examiner believes there are any additional issues that have not been resolved, the Examiner is invited to call the undersigned representative who is attorney of record in this case.

The Commissioner is hereby authorized to charge our Deposit Account No. 190734, should additional fee(s) be required, or credit any overpayment, in the filing of this document to expedite the prosecution of this application.

Respectfully submitted,

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